

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA :
 :
 v. : **CRIMINAL NO. 19-319-01**
 :
 LEANDRO RODRIGUEZ :

GOVERNMENT’S CHANGE OF PLEA MEMORANDUM

I. Introduction

In an indictment unsealed June 11, 2019, defendant Leandro Rodriguez is charged with a multi-object conspiracy: to defraud the United States by impeding and impairing the lawful functions of the Food and Drug Administration (“FDA”), and to commit two offenses against the United States: smuggling (in violation of 18 U.S.C. § 545), and receiving in interstate commerce misbranded drugs and delivering and proffering delivery of those drugs for pay, with intent to mislead (in violation of 21 U.S.C. §§ 331(c) and 333(a)(2) and 18 U.S.C. § 2), all in violation of 18 U.S.C. § 371 (Count One). The charges arise from the defendant’s membership in a conspiracy in operation from early 2011 until March 31, 2017, to import from China and resell to consumers, substances that purported to be “all natural” dietary supplements but which the defendant knew contained the undeclared ingredient Sibutramine, a dangerous controlled substance that could not legally be sold in the United States.

The Court has scheduled a plea hearing for the defendant for Monday, October 18, 2021, at 11 a.m.

II. No Guilty Plea Agreement

There is no guilty plea agreement between the parties. Instead, counsel has represented that defendant Rodriguez intends to enter a plea of guilty to Count One, the count of the indictment in which he is charged.

III. Statute and Essential Elements of the Offense

Conspiracy to Defraud the United States, Commit Smuggling and Violate the FDCA -- 18 U.S.C. § 371 (Count 1)

The defendant is charged with a multi-object conspiracy, to defraud the United States by impairing and impeding the lawful functions of the FDA, and commit two offenses: smuggling (in violation of 18 U.S.C. § 545), and receiving in interstate commerce misbranded drugs and delivering and proffering delivery of those drugs for pay, with intent to mislead (in violation of 21 U.S.C. §§ 331(c) and 333(a)(2) and 18 U.S.C. § 2). To convict the defendant of this conspiracy, the government must prove beyond a reasonable doubt:

1. That two or more persons agreed to defraud the United States or commit an offense against the United States, as charged in the indictment;
2. That the defendant was a party to or member of that agreement;
3. That the defendant joined the agreement or conspiracy knowing of its objective to defraud the United States or commit offenses against the United States and intending to join together with at least one other alleged conspirator to achieve one or more of those objectives; that is, that the defendant and at least one other alleged conspirator shared a unity of purpose and the intent to achieve a common goal or objective, to defraud the United States or commit offenses against the United States; and
4. That at some time during the existence of the agreement or conspiracy, at least one of its members performed an overt act in order to further the objectives of the agreement.

Third Circuit Model Criminal Jury Instruction 6.18.371A, B (2012).¹

¹ The notion of impeding a government function is quite broad and extends to a wide array of deceptive conduct. Section 371's defraud prong places no condition on the method used to defraud the United States and it reaches any interference or obstruction of a lawful government function by deceit, craft or treachery or at least by means that are dishonest. *See Dennis v. United States*, 384 U.S. 855, 860-61 (1966). In addition to the objective of defrauding the United States, the other two objectives of the conspiracy were to commit two underlying crimes: smuggling in violation of 18 U.S.C. § 545, and receiving in interstate commerce misbranded drugs and delivering and proffering delivery of those drugs for pay, with intent to mislead, in violation of 21 U.S.C. §§ 331(c) and 333(a)(2) and 18 U.S.C. § 2. The elements of smuggling in violation of 18 U.S.C. § 545 are that the defendant brought diet drugs into the United States; that he knew that the diet drugs should have been declared or reported to customs authorities as required by

IV. Maximum Penalties

The defendant faces the following maximum sentence:

Count 1 – Conspiracy, in violation of 18 U.S.C. § 371 – 5 years of imprisonment, 3 years of supervised release, a \$250,000 fine, a \$100 special assessment, and forfeiture.

Total Maximum Sentence: 5 years of imprisonment; 3 years of supervised release; a \$250,000 fine, a \$100 special assessment, restitution in the amount of \$669,279 and forfeiture of \$669,279.

V. Sentencing Guidelines

The advisory Sentencing Guidelines apply to this case. Counsel for the government estimates the guidelines as follows:

- A base offense level of 6 applies under USSG §2B1.1(a)(2).
- 14 offense levels are added because the intended loss is more than \$550,000 and less than \$1,500,000, measuring intended loss by the estimated street value of the controlled substances, per USSG § 2B1.1(b)(1)(H) and Application Note 3(F)(vi).

law; and that the defendant acted knowingly and willfully with intent to defraud the United States. As to introducing misbranded drugs into the United States, section 331 of the Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 331, lists prohibited acts, including in part (a), “the introduction or delivery for introduction into interstate commerce of any food [or] drug. . .that is adulterated or misbranded.” Under section 352 of the Act, 21 U.S.C. § 352, a drug is misbranded several ways, including, as relevant here, if it bears a false or misleading label, or if its label does not bear the established name and quantity of each active ingredient. Here, the purported dietary supplements imported and sold by the defendants were misbranded because they contained Sibutramine, which did not appear on the label. Section 333(a) of the Act, 21 U.S.C. § 333(a), makes violations of § 331 committed with intent to defraud or mislead, felony violations. In this case, the government would prove that defendant Rodriguez intended to defraud or mislead the regulatory authorities who would have seized the products had their ingredients been properly identified. The elements of felony introduction of misbranded drugs into interstate commerce are: (1) that the diet pills were drugs under the FDCA; (2) that the diet pills were misbranded, in that their labeling was false and misleading by, among other things, purporting to be a dietary supplement and by not identifying the active ingredient Sibutramine on the label, and misbranded by not identifying all the ingredients on the label as required; (3) that the defendant acted with the intent to defraud or mislead; and (4) that the diet pills were introduced into interstate commerce.

- 2 offense levels are added because the offense involved 10 or more victims, per USSG § 2B1.1(b)(2)(A)(i).
- 2 more offense levels are added because the offense involved the conscious or reckless risk of death or serious bodily injury within the meaning of USSG § 2B1.1(b)(16)(A).
- As of the date of the plea hearing, defendant Rodriguez has accepted responsibility for his offense, making the defendant eligible for a two-level downward adjustment under USSG § 3E1.1(a).
- As of the date of the plea hearing, the defendant has assisted authorities in the investigation or prosecution of his own misconduct by timely notifying the government of his intent to plead guilty, thereby permitting the government to avoid preparing for trial and permitting the government and the court to allocate their resources efficiently, resulting in a one-level downward adjustment under USSG § 3E1.1(b), for a final offense level of 21.

Counsel for the government is not aware of any prior criminal history. A person with no criminal history points is in Criminal History Category (“CHC”) I. If the defendant is in Criminal History Category I, then with an offense level of 21, he faces a range of 37 to 46 months in prison. This is only an estimate; the defendant could face a higher advisory guideline range if he has countable criminal convictions.

VI. Factual Basis for the Plea

At trial, the United States would prove beyond a reasonable doubt, facts including, but not limited to, the following:

Count One

By means of documents and testimony from government officials, the United States would prove the following background facts: the FDA is the federal agency within the Department of Health and Human Services responsible for protecting the health and safety of the American public by, among other things, ensuring that drugs sold in the United States are safe and effective for their intended uses, and that labeling for drugs bear true and accurate

information. FDA carries out these responsibilities through enforcement of the federal Food, Drug and Cosmetic Act (“FDCA” or “the Act”) and regulations promulgated pursuant to the Act.

The FDCA defines “drug” to include articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, and articles (other than food) intended to affect the structure or any function of the human body. It is illegal under federal law to import drugs into the United States, or to sell any drug that has not been approved by FDA for use in the United States.

The Drug Enforcement Administration (“DEA”) is the federal agency which regulates the distribution of certain prescription medications which contained controlled substances. Controlled substances may not be possessed without a valid prescription, nor may they be prescribed or distributed without proper certification from DEA.

Sibutramine is a Schedule IV controlled substance, which may not lawfully be distributed or dispensed without proper authorization and licensing from DEA. Also, any pills or capsules containing Sibutramine require approval by FDA before being made available for use in the United States. Sibutramine was the active ingredient in Meridia®, a prescription drug that was manufactured by Abbott Laboratories and approved by FDA to treat obesity. In October 2010, FDA requested Abbott to withdraw Meridia® from the market due to cardiovascular events and strokes. Previously, in November 2009, FDA publicized its concerns about the increased risk of heart attack, stroke and death posed by Meridia® and the agency requested that the market add a contraindication to Meridia’s® label for people with a history of cardiovascular disease. On December 21, 2010, at the request of the manufacturer, FDA withdrew its approval of Meridia®. *See* 75 Fed. Reg. 80061 (December 21, 2010).

Tadalafil is the active ingredient in Cialis®, a prescription drug manufactured by

Lilly ICOS LLC (hereinafter “Lilly”). Cialis®, which is a trademark of Lilly, was approved by the FDA for the treatment of erectile dysfunction in men and the signs and symptoms of benign prostatic hyperplasia. During the indictment period, FDA had not approved a generic drug containing tadalafil.

From January 2011 until March 2017, defendants Leandro Rodriguez, Eric Trevino and Jaime Carrillo Haro (now deceased) participated in a conspiracy with three objects: first, to defraud FDA by thwarting its roles in regulating the interstate sale and distribution of drugs in the United States and safeguarding the health and safety of consumers who purchase drugs in the United States; second, to violate 18 U.S.C. § 545 by illegally importing misbranded diet drugs containing Sibutramine, a Schedule IV controlled substance, from China; and third, to violate 21 U.S.C. §§ 331(a), 352(a) and (e) and 333(a)(2) by receiving misbranded drugs into interstate commerce with the intent to defraud and mislead, and delivering and proffering delivery of those drugs for pay or otherwise. The evidence would show that defendant Rodriguez took pre-paid drug orders from Trevino and his brother-in-law, Carrillo Haro, then imported the drugs from China, disguising the nature of the drugs, and shipped them to Trevino and Carrillo using false names. In furtherance of the conspiracy, defendants Trevino and Carrillo Haro paid defendant Rodriguez more than \$669,000 in payment for the misbranded drugs that the group imported unlawfully from China.

This defendant, Leandro Rodriguez, who imported the drugs from China, lived in Allentown, Pennsylvania and owned a mail order business called Lean On Nature, LLC. Defendants Trevino and Carrillo Haro lived in the Southern District of Texas, near the Mexico border. Carrillo Haro sold the diet drugs wholesale, as well as at a flea market in McAllen TX, while Trevino sold them to consumers throughout the United States, Canada, Australia and Great

Britain through his website, www.botanicalnow.com. Both men falsely touted the diet drugs they bought from defendant Rodriguez as “herbal” and “all natural,” even though both knew that the diet drugs contained Sibutramine, a dangerous drug that did not appear on the label.

To prove the conspiracy, the government would present extensive email and text message contact between and among Rodriguez, Trevino and Carrillo, along with over seven years of bank records of the businesses that the defendants used to conduct their drug trafficking operation, that is, Lean on Nature LLC (Rodriguez); Mary’s Health and Beauty (Trevino); and Amigo Natural Products (Carrillo Haro). The bank records would be summarized by an agent who analyzed them. They show that defendants Trevino and Carrillo Haro paid Rodriguez more than \$669,000 for the misbranded drugs that the group imported from China. The government would introduce defendant Rodriguez’s handwritten ledger of the drugs that he was ordering from China, then shipping and selling to defendants Trevino and Carrillo Haro, which ledger is dated from early 2012 until March 2017, and which was seized from Rodriguez’s residence in March 2017 pursuant to a federal search warrant. The government would introduce PayPal records showing that defendant Rodriguez sent funds to China in order to buy diet drugs on behalf of defendants Trevino and Carrillo Haro. In addition, the government would introduce delivery records from delivery services DHL and TNT, as well as the United States Postal Service, showing that defendant Rodriguez received approximately 68 parcels from China between March 2011 and August 2015. These delivery records are all falsely labeled, showing what was delivered as other items, not diet drugs and not dietary supplements.

At trial, the government would introduce Federal Express records showing that defendant Rodriguez shipped numerous packages to defendants Trevino and Carrillo Haro. Specifically, from February 5, 2015 to November 21, 2016, approximately 37 parcels weighing a

total of 901 pounds were shipped via FedEx Ground from Rodriguez's business, Lean on Nature, to "Jose Rodriguez" at Eric Trevino's home address. However, during this time, no one named Jose Rodriguez ever lived at Trevino's address. The Federal Express records would show further that from January 19, 2015 to March 6, 2017, approximately 109 parcels weighing a total of 2,683 pounds were shipped via FedEx Ground from Lean on Nature to Amigo Natural Products or Elida Carrillo (but never to Jaime Carrillo Haro).

To prove that during the conspiracy period, defendant Rodriguez knew that it was illegal to import, purchase and sell the purported dietary supplements because they contained Sibutramine, the government would introduce testimony of co-defendant Eric Trevino, who would testify pursuant to a cooperation guilty plea agreement. Trevino would testify that on or about April 6, 2011, when he (Trevino) had already begun purchasing the diet drugs from Rodriguez, he (Trevino) was interviewed by two special agents of FDA-OCI. Trevino would introduce into evidence an FDA News Release that he signed that day, April 6, 2011. The FDA News Release that Trevino signed on April 6, 2011 warns of the health danger posed by a number of diet drugs that Trevino was selling, explaining that they contain undeclared prescription drugs such as Sibutramine, that could cause significant side effects in some people, including nausea, vomiting, elevated blood pressure, heart attacks and strokes. Trevino would testify that within two weeks of the interview, he telephoned Rodriguez and told Rodriguez that the agents had told him that the imported weight loss supplements he (Trevino) was buying from defendant Rodriguez contained Sibutramine, which was a dangerous controlled substance. Trevino would testify that he also told Rodriguez that he had told the agents that he (Trevino) was buying the diet drugs from Rodriguez, and that he (Trevino) had told the agents that if it was against the law to be selling the pills he was selling, he did not want to sell them any more. In

addition, the government would introduce another, unsigned copy of the FDA News Release, bearing a print-out date of 4/11/2011, less than a week after Trevino and Carrillo Haro had been interviewed by FDA-OCI agents. This unsigned copy of the FDA News Release was seized from inside defendant Rodriguez's garage during the warranted search of Rodriguez's residence on March 16, 2017.

During that search, agents also found a seizure notice from U.S. Customs and Border Protection ("CBP"), addressed to the defendant, dated October 14, 2015, concerning CBP's seizure of tadalafil worth \$2,818 at JFK Airport on October 1, 2015. The seizure notice warned Rodriguez that the tadalafil was subject to forfeiture as a prescription drug, and further that its importation was prohibited by the FDA. The seizure notice was found inside Rodriguez's safe; an agent would testify that Rodriguez told the agents on the day of the search that he had put the seizure notice inside his safe. Also during the search, Rodriguez's cellular phone was seized and searched under warrant. It was found to contain contact cards for Carrillo and Trevino, and many text messages between Rodriguez and Carrillo, discussing problems with pills being seized by CBP; Carrillo's purchases of diet pills from Rodriguez; and Carrillo's sales of diet pills to customers in the McAllen Texas area. In addition, the government would introduce in evidence a parcel addressed to Lean on Nature at the defendant's Allentown address that was seized March 9, 2017. When searched pursuant to warrant, the parcel was found to contain 500 bottles of Lida Daidaihua weight loss capsules. Laboratory analysis showed that the pills contain Sibutramine, but the labels do not list this ingredient.

The government would introduce emails from defendant Rodriguez's email account, seized via search warrant on December 30, 2016. These would include emails in which Rodriguez communicated with Trevino about diet drugs containing Sibutramine. For example,

the government would introduce an email from Rodriguez to Trevino dated January 13, 2011, where, in response to an email from Trevino asking about Rodriguez's ability to supply 500 bottles of Meizitang (a diet drug on the FDA News Release), Rodriguez says, "[e]stas es la pastilla meizitang with sibutramine." Translated, this means, this is the pill Meizitang with sibutramine. The government would also introduce emails from the leanflava account in which Rodriguez communicated with his Chinese sources about how to pay for the drugs via a link that hid the nature of the products (e.g., describes what is being sold as a "plush Shaun the Sheep toy") in order to hide the nature of the transactions. The emails from the leanflava account also include an October 13, 2015 email from Rodriguez to his Chinese sources, directing his Chinese sources to change the name on the label of certain products containing Sibutramine because, in Rodriguez's words, the products were on an FDA Watch list. In a later email from the leanflava account, dated February 18, 2016, Rodriguez explains to a different Chinese source, "here I cannot send by local post cause these products here in usa not approved by fda, . . ." The government would also introduce emails from defendant Trevino's email account, stanfordgolf02@aol.com, seized via warrant on August 24, 2017. This evidence would include an email from Rodriguez to Trevino dated April 10, 2011, less than a week after Trevino was interviewed by FDA agents, in which Rodriguez says that he is very sorry about what happened.

The United States respectfully submits that based on the above summary of evidence, there is a factual basis for Mr. Rodriguez's plea of guilty to Count One of the Indictment.

JENNIFER ARBITTIER WILLIAMS
Acting United States Attorney

s/Mary E. Crawley
MARY E. CRAWLEY
Assistant United States Attorney

DATE: October 14, 2021

CERTIFICATE OF SERVICE

I hereby certify that I have caused to be served a true and correct copy of the Government's Guilty Plea Memorandum on this date, by e-mailing, to the following:

Kathryn E. Roberts, Esquire
527 Hamilton Street
Allentown PA 18101
Kathryn_Roberts_Esquire@yahoo.com
Counsel for Leandro Rodriguez

s/Mary E. Crawley
MARY E. CRAWLEY
Assistant United States Attorney

DATE: October 14, 2021